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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte FRED WEHLING,
MARY ALDRITT,
ROBERT E. LEE,
and
JASON KALLESTAD,
Appellants¹

Appeal 2009-008111
Application 10/743,118
Technology Center 1600

Decided: May 17, 2010

Before CAROL A. SPIEGEL, DEMETRA J. MILLS, and
STEPHEN WALSH, *Administrative Patent Judges*.

SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants appeal under 35 U.S.C. § 134(a) from an Examiner's final rejection of all pending claims, claims 1, 3, and 5-36. Oral arguments were held May 11, 2010. We have jurisdiction under 35 U.S.C. § 134. We REVERSE.

¹ The real party in interest is AMERILAB TECHNOLOGIES, INC. (Substitute Appeal Brief filed 20 August 2007 ("App. Br.") at 3).

I. Statement of the Case

The subject matter on appeal is directed to effervescent compositions containing menthol and eucalyptus oil and uses thereof. Claims 1, 21, 29, 31, 33, and 34 are illustrative and read (App. Br. Claims App'x):

1. A tablet comprising an effervescent composition comprising:
from 0.5% by weight to about 10% by weight menthol;
from 0.5% by weight to about 10% by weight eucalyptus oil; and
an effervescent agent comprising an acid and a base;
wherein the tablet dissolves in water having a temperature of at least 38°C to form a clear solution.

33. A method of using the tablet of claim 1, said method comprising dissolving the tablet of claim 1 in water to form a clear solution; and inhaling vapors emitted by the solution.

34. A method of using the tablet of claim 1, said method comprising dissolving the tablet of claim 1 in water to form a clear solution; and gargling with said solution.

21. A tablet comprising an effervescent composition comprising:
from 0.5% by weight to about 10% by weight menthol;
from 0.5% by weight to about 10% by weight eucalyptus oil; and
an effervescent agent comprising an acid and a base;
the tablet having a hardness of at least 10 kilopounds and dissolving in water having a temperature of at least 38°C in less than 120 seconds.

29. An effervescent composition comprising:
menthol;
eucalyptus oil; and
an effervescent agent comprising an acid and a base,
the composition dissolving in water having a temperature of about 38°C to form a clear solution.

31. A carbonated mouthwash comprising:
water;
menthol; and
eucalyptus oil.

Claim 8 requires the tablet of claim 1 to have a hardness of at least 15 kilopounds. Claims 35 and 36 require the water used in the method of claim 33 to be at a temperature of at least 38°C or boiling, respectively.

We interpret the claim term "a clear solution," consistent with the 118 specification, to be a solution that is visibly free of suspended particulate matter, floating scum, and sediment (precipitation) (Specification 1:17-22; 8:14-19; 10:3-13).

The Examiner has rejected claims 1, 3, and 5-36 as obvious under 35 U.S.C. § 103(a) over Gioffre² in view of Schobel³ OR Rockliffe⁴ OR Andersen⁵ (Ans.⁶ 3-6).

The Examiner found that Gioffre discloses a chewable effervescent tablet comprising menthol, eucalyptus oil, and a gas containing inorganic oxide material as an effervescent agent (Ans. 3-4). The Examiner found that Schobel teaches an effervescent tablet comprising a therapeutic agent, a granulating agent, a microparticulate effervescent component, and an

² U.S. Patent 4,627,972, *Effervescent Dentifrice*, issued 9 December 1986, to Gioffre et al. ("Gioffre").

³ U.S. Patent 4,687,662, *Therapeutic Effervescent Composition*, issued 18 August 1987, to Alexander M. Schobel ("Schobel").

⁴ U.S. Patent 4,471,871, *Packaged Dry-to-the-Touch Article and Method of Packaging the Article*, issued 18 September 1984, to Rockliffe et al. ("Rockliffe").

⁵ U.S. Patent 3,629,468, *Hygroscopically Controlled Effervescent Mouthwash Tablet*, issued 21 December 1971, to Howard P. Andersen ("Andersen").

⁶ Examiner's Answer mailed 30 November 2007 ("Ans. ").

effervescent system, and that the tablet rapidly dissolves in water at 22°C (*id.* at 4). According to the Examiner, the

recitation/limitation of instant claim 1 (tablet dissolves in water having a temperature of at least 38°C to form a clear solution) is an inherent feature and as long as all critical elements (structure and composition) as required by instant claims are taught by the cited reference and thus the claims are anticipated [*id.* at 4].

The Examiner also found that Rockliffe discloses a packaging kit for tablets which seals the tablets in an air-tight container which is impervious to water (Ans. 5). Apparently, the Examiner found that this disclosure renders claims 27-29 anticipated (*id.* ("Regarding the claims 27-29 ...")).

The Examiner further found that Andersen teaches dissolving an effervescent tablet in water to produce a solution useful as a mouthwash (Ans. 5). "Regarding claims 35 and 36, ... when these references [Gioffre and Andersen] are taken together, water temperature is obvious because of the prior art teaching of dissolution of effervescent tablets to provide a clear solution, which makes it uniquely desirable for use as mouthwash" (*id.*).

Appellants contend that the Examiner has not clearly articulated the manner in which the references are being combined to establish a *prima facie* conclusion of obviousness (see e.g., App. Br. 12-13). Appellants note with concern the statement in the Examiner's Answer at page 4 that claim 1 is anticipated by the "cited reference" (Reply Br.⁷ 2).

Appellants essentially argue that Gioffre fails to teach or suggest a

(i) tablet containing both menthol and eucalyptus oil (claims 1, 21, and 31),

⁷ Reply Brief filed 29 January 2008 ("Reply Br.").

- (ii) tablet which dissolves in water having a temperature of at least 38°C to form a clear solution (claim 1) or which dissolves in less than 120 seconds (claim 21),
- (iii) tablet having the claimed hardness (claims 8, 9, 21, 23, and 24),
- (iv) mouthwash containing both menthol and eucalyptus oil (claim 31),
- (v) method of dissolving the tablet of claim 1 in water to form a clear solution and inhaling vapors emitted by the solution (claims 33 and 35), specifically in boiling water (claim 36), or
- (vi) method of dissolving the table of claim 1 in water to form a clear solution and gargling with the solution (claim 34) (App. Br. 11-12 and 17-21).

Appellants note that Gioffre teaches that its chewable dentifrice tablets are unique in providing effervescence without the need of a chemical acid/base reaction (App. Br. 12). Appellants contend that none of Schobel, Rockliffe, or Andersen cures these deficiencies in Gioffre (*id.* at 12, 14, 15, 17, 18, 21, and 22). In particular, Appellants argue that there is no apparent reason to combine the teachings of Gioffre and Schobel because Schobel's tablets are intended to be ingested, whereas Gioffre's are not (*id.* at 14-15). Appellants further argue that a single disclosure of a hardness of 7-9 strong cobb units (5-6.4 kilopounds) for the tablet described in Schobel Example 1 does not teach or suggest tablets having the claimed hardness or any reason for providing the claimed hardness in a chewable tablet (*id.* at 16-17). Appellants specifically argue that Andersen does not teach or suggest that all tablet formulations are suitable for forming a mouthwash or how to modify the tablet of Gioffre to form a mouthwash (*id.* at 19).

The dispositive issue in this case is whether the Examiner has explicitly articulated a *prima facie* case of obviousness which addresses all of the limitations of the claimed invention.

II. Findings of Fact

The following findings of fact ("FF") are supported by a preponderance of the evidence of record.

A. Gioffre

- [1] Gioffre describes dentifrice compositions which provide effervescent/mechanical cleaning actions during use (Gioffre 1:64-65).
- [2] The dentrifrice composition comprises an essentially anhydrous dentrifrice base medium and an inorganic oxide material, such as a zeolite molecular sieve, containing an adsorbed gas, e.g., carbon dioxide, that is released upon contact with water (Gioffre 1:66-2:2; 2:25-32; 3:9-15).
- [3] According to Gioffre, its composition is "unique in providing effervescent action without the need of the chemical acid/base reactions as heretofore employed in dentrifrice compositions" (Gioffre 2:22-25).
- [4] However, "an acid/base reaction couple may be employed when an additional in situ source of a gas is desired" (Gioffre 8:28-31).
- [5] According to Gioffre, the mean particle size of the gas-containing inorganic oxide is preferably less than 10 microns and preferably has a particle size distribution with less than 10% by weight of the particles having a particle diameter greater than 5 microns (Gioffre 3:42-47).

- [6] In addition, any suitable flavoring or sweetening agent or mixtures thereof may be added to the composition in amounts from about 0.1 to 10% or more (Gioffre 4:23-24 and 54-56).
- [7] Exemplary flavorants include menthol and eucalyptus oil, while exemplary sweeteners include sucrose and sorbitol (Gioffre 4:25-54).
- [8] A waxy matrix, such as polyethylene glycol having a molecular weight of about 6,000, is generally added in amounts between about 4 and about 20% by weight to facilitate formation of chewable dental tablets (Gioffre 7:16-23).
- [9] Various solid ingredients are usually added when preparing dentifrice powders (Gioffre 7:10-15).

B. Schobel

- [10] Schobel describes a therapeutic effervescent composition comprising (A) a mixture of (1) a granulated therapeutic agent having a particle size of about 100 to about 600 microns and (2) a component of an effervescent system having a particle size of about 50 to about 600 microns, and (B) an effervescent system, which dissolves in water to yield an effervescent solution containing completely dissolved therapeutic agent (Schobel 1:11-14; 2:16-27).
- [11] The therapeutic agent can be any soluble or slightly soluble therapeutic agent or nutrient suitable for oral administration in an aqueous solution (Schobel 3:9-12).
- [12] The granulating agent can be any water soluble pharmaceutically acceptable granulating agent having a viscosity below 100 cps and compatible with the therapeutic agent (Schobel 4:13-17).

- [13] The microparticulate component of the effervescent system may be a carbonate containing material, e.g., sodium carbonate or sodium bicarbonate (Schobel 4:54-56; 5:48-60).
- [14] According to Schobel, a granulated particle size of less than 100 microns yields a chalky material which results in processing problems such as poor mixing and compressibility properties (Schobel 4:35-38).
- [15] Similarly, a component of the effervescent system having a particle size less than 50 microns promotes excessive static charge and will not mix uniformly with the granulated component (Schobel 4:60-64).
- [16] Flavoring agents, such as mints, menthol, artificial vanilla, various fruit flavors, both individual and mixed, and the like may be added in amounts ranging from about 0.5 to about 3% by weight (Schobel 6:16-23).
- [17] Example 1 describes an embodiment comprising (A) a mixture containing acetaminophen and microparticulate citric acid and (B) an acid/base effervescent system which is compressed into tablets with a hardness of 7-9 strong cobb hardness units and which disintegrate in 55 seconds with no undissolved drug residue when placed in water at 22°C (Schobel 7:48-8:29).

C. Rockliffe

- [18] Rockliffe discloses a method of packaging an article comprising a polymeric matrix containing a non-aqueous liquid in a closed, moisture impervious container (Rockliffe 1:5-17).
- [19] The article delivers the non-aqueous liquid as and when desired to provide any of a variety of functions, such as cleaning or deodorizing, when the article is moistened with water (Rockliffe 1:9-17).

D. Andersen

- [20] Andersen discloses mouthwash tablets comprising a combination of germicidal and breath-freshening agents, an acid/base system for generating effervescence, sweeteners, and flavoring ingredients (Andersen 2:40-46; 2:72-3:3).
- [21] According to Andersen, the effervescence is initiated by contacting the tablet with the saliva and/or a small quantity of water added to the mouth of the user (Andersen 3:3-7).
- [22] Suitable flavoring ingredients include peppermint and cinnamon in amounts ranging from about 0.2 to 5.0% by weight (Andersen 3:69-73).

III. Discussion

A. Legal principles

Anticipation requires that a prior art reference describe every limitation in a claim either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.” *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 12689 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). When determining whether a claim is obvious, an Examiner must make "a

searching comparison of the claimed invention – *including all its limitations* – with the teachings of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Int'l. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Furthermore, in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), the Supreme Court noted that "[t]o facilitate review, this [obviousness] analysis should be made explicit."

B. Analysis

Here, the Examiner has failed to perform the necessary fact finding and legal analysis necessary to establish a *prima facie* case of unpatentability, whether based on anticipation under 35 U.S.C. § 102(b) or obviousness under 35 U.S.C. § 103(a). Indeed, the Examiner's position is often confusing and unclear.

To the extent the Examiner's Answer suggests that certain claims are "anticipated," it does not support a *prima facie* case of anticipation because the Examiner has not identified the anticipatory reference being relied on and/or how the reference describes every limitation in the claim. For example, it is unclear what "cited reference" the Examiner is referring to on page 4 of the Answer as "anticipating" the "instant claims." The Examiner also found claims 27-29 "anticipated" by Rockliffe's disclosure of an air-tight, water impervious packaging kit for tablets (Ans. 5). However, the Examiner did not explain where Rockliffe disclosed a tablet/composition which dissolves in water having a temperature of about 38°C to form a clear solution as required by claims 27-29.

Similarly, the Examiner's Answer does not support a *prima facie* case of obviousness over Gioffre in view of Schobel OR Rockliffe OR Andersen. We begin our analysis with the rejection based on the combined teachings of Gioffre and Schobel.

There are four independent claims on appeal, claims 1, 21, 29, and 31. Claims 1 and 29 recite a tablet or a composition which dissolves in water having a temperature of about 38°C to form a clear solution. According to the Examiner, on the one hand this is a property of Gioffre's tablet (Ans. 8, ¶ 2) and on the other hand Schobel shows an effervescent system which dissolves rapidly in water to yield a clear solution (*id.* at last ¶). More specifically, the Examiner states that the

composition of Gioffre would inherently dissolve in water, it is noted that the dissolution of tablet in water is a property of the tablet and Schobel further teaches that the dissolution of the tablet occurs at 22°C temperature of water. It is further noted that recitation/limitation of tablet dissolves in water having a temperature of at least 38°C to form a clear solution is inherent feature and as long as all critical elements as required by instant claims are taught by the cited reference and thus the claims are anticipated [Ans.¶ bridging 9-10.].

The Examiner concludes that it would have been obvious to combine the compositions of Gioffre and Schobel to obtain a third composition useful for the same purpose (*id.* at ¶ bridging 8-9).

However, as pointed out by Appellants (Reply Br. 3), the inorganic oxide materials of Gioffre are water-insoluble materials (FF 2). The particulates and granulating agents of Schobel are water-soluble materials (FF 12-13). Further, the mean particle size of Gioffre's inorganic oxide material is preferably less than 10 microns (FF 5). Schobel teaches that

granulated particles of less than 100 microns yield a chalky material with poor mixing and compressibility properties (FF 14) and effervescent particles less than 50 microns promote excessive static charge and will not mix uniformly with the granulated component (FF 15). In addition, Gioffre adds a waxy matrix to facilitate formation of chewable dental tablets (FF 8) or various solid ingredients to prepare dentifrice powders (FF 9). Thus, we agree with Appellants that the Examiner has failed to articulate a reasoned/factual basis for combining the compositions of Gioffre and Schobel with a reasonable expectation of success of obtaining a tablet which dissolves in water having a temperature of about 38°C to form a clear solution as required by claims 1 and 29 and claims dependent thereon.

At a minimum, the Examiner has not explained why one of ordinary skill in the art would have reasonably expected the water-insoluble inorganic oxide materials of Gioffre to form a "clear solution" in water as claimed. Furthermore, consistent with Schobel's discussion of the effects of particles of less than 50-100 microns in size, Gioffre discloses adding waxy materials or various solids to produce chewable tablets or powders. Similarly, the Examiner has not explained why one of ordinary skill in the art would have reasonably expected tablets containing waxy materials to form a "clear solution" in water as claimed. In short, it is unclear how and why Gioffre and Schobel are being combined.

Therefore, we reverse the rejection of claims 1 and 29 and claims dependent thereon under § 103 over the combined teachings of Gioffre and Schobel.

Claim 21 recites a tablet having a hardness of at least 10 kilopounds and which dissolves in water having a temperature of about 38°C in less than

120 seconds. The Examiner points to Schobel as teaching a tablet having hardness of 7-9 strong cobb units (i.e., about 5 to about 6.4 kilopounds) and challenges Appellants to show that a hardness of 10-15 kilopounds provides unexpected results (Ans. 10). As pointed out by Appellants (App. Br. 17-18), the Examiner has failed to explain why one of ordinary skill in the art would have reasonably expected the Gioffre/Schobel tablet to dissolve in water at about 38°C given the water-insoluble inorganic oxides of Gioffre, the waxy matrix added to the formulation of Gioffre in order to form tablets of Gioffre, and the effect of the particle sizes as taught and discussed by Gioffre and Schobel on the resulting effervescent tablet. The Examiner has also failed to explain why it would have been obvious to produce tablets having a hardness value two to three times that taught in Example 1 of Schobel, e.g., what effect on dissolution reasonably might be expected.

Therefore, we reverse the rejection of claim 21 and claims dependent thereon under § 103 over the combined teachings of Gioffre and Schobel.

Claim 31 recites a carbonated mouthwash comprising water, menthol, and eucalyptus oil. As pointed out by Appellants (App. Br. 18), neither Gioffre nor Schobel teach or suggest a mouthwash, let alone a mouthwash containing both menthol and eucalyptus oil. Apparently, the Examiner relies on Andersen in addition to Gioffre and Schobel to reject claim 31 (see e.g., Ans. 5, ¶ 2 and 6, ¶ 3). However, since that is not the stated rejection before us, we also reverse the rejection of claim 31 under § 103 over the combined teachings of Gioffre and Schobel.

As to the rejection based on Gioffre and Rockliffe, the Examiner has not explained how the combined disclosures of Gioffre and Rockliffe would have taught or suggested all of the claim limitations to one of ordinary skill

in the art. For example, the Examiner has not explained why Rockliffe's disclosure of packaging an article in a closed, moisture impervious container (FF 18) in combination with Gioffre's water-insoluble inorganic oxide materials would have taught or suggested a tablet/composition which forms a "clear solution" in water or a carbonated mouthwash as claimed. Indeed, it appears that the Examiner is only applying Rockliffe to the subject matter of claims 27-29 (see e.g., Ans. ¶ 1; 10, ¶ 3). Absent a fact-based analysis which explicitly compares all the limitations of the claimed invention with the combined teachings of Gioffre and Rockliffe, we are constrained to reverse the rejection of claims 1, 21, 29, and 31 and the claims dependent thereon under § 103 over the combined teachings of Gioffre and Rockliffe.

The rejection under § 103 based on Gioffre and Andersen is similarly problematic because the Examiner has not set forth a fact-based analysis explicitly comparing all the limitations of at least independent claims 1, 21, 29, and 31 with the combined teachings of Gioffre and Andersen. Again, it appears that the Examiner is only applying Andersen to the subject matter of claims 31, 35, and 36 and, then, only in combination with Gioffre and Schobel (Ans. 5, ¶ 2; 6, ¶ 3). In particular, it appears that this rejection is based upon the assumption that the tablet/composition of Gioffre dissolves in water having a temperature of about 38°C to form a clear solution. Absent a sufficient factual basis or reasoned rationale establishing such an assumption as a reasonable conclusion based on the applied evidence of record, the Examiner's position is unsustainable. Therefore, we must reverse the rejection of claims 1, 21, 29, and 31 and the claims dependent thereon under § 103 over the combined teachings of Gioffre and Andersen.

C. Conclusion

The rejections of claims 1, 3, and 5-36 under § 103 over Gioffre in view of any of (I) Schobel or (II) Rockliffe or (III) Andersen are reversed because the Examiner has failed to explicitly articulate a *prima facie* case of obviousness which addresses all of the limitations of the claimed invention.

IV. Order

Upon consideration of the record, and for the reasons given, it is

ORDERED that the decision of the Examiner to reject claims 1, 3, and 5-36 as unpatentable under 35 U.S.C. § 103(a) over Gioffre in view of Schobel is REVERSED,

FURTHER ORDERED that the decision of the Examiner to reject claims 1, 3, and 5-36 as unpatentable under 35 U.S.C. § 103(a) over Gioffre in view of Rockliffe is REVERSED, and

FURTHER ORDERED that the decision of the Examiner to reject claims 1, 3, and 5-36 as unpatentable under 35 U.S.C. § 103(a) over Gioffre in view of Andersen is REVERSED.

REVERSED

alw

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